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### **DETAILED ACTION**

1. Claims 27, 32, 40 and 42-43 are pending.

- 2. The rejection of claims 3-5, 32 and 40-42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is obviated by Applicant's amendment or cancellation of the claims.
- 3. The rejection of claims 1-4, 7, 16-23, 25-26, 30-31, 33 and 35-39 under 35 U.S.C. 102(b) as being anticipated by Daniell et al (2001, Curr. Genet. 39:109-116) taken with the evidence of the instant specification is obviated by Applicant's cancellation of the claims.
- 4. The rejection of claims 1-4, 7, 11-12, 16-17, 20-23, 25-27, 30-33, 35-37 and 39 under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) is obviated by Applicant's amendment or cancellation of the claims.
- 5. The rejection of claims 5-6 and 15 under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) as applied to claims 1-4, 7, 11-12, 16-17, 20-23, 25-27, 30-33, 35-37 and 39 above, and further in view of Maliga et al (1999, US patent 5,877,402) is obviated by Applicant's cancellation of the claims.
- 6. The rejection of claims 6 and 8-9 under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) as applied to claims 1-4, 7, 11-12, 16-17, 20-23, 25-27, 30-33, 35-37 and 39 above, and further in view of McBride et al (1999, US patent 5,925,806) is obviated by Applicant's cancellation of the claims.

7. The rejection of claims 1, 11-12, 17, 22-23, 26, 30-31, 33, 35-37 and 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-121 of U.S. Patent No. 7,129,391 is obviated by Applicant's cancellation of the claims.

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- 8. The rejection of claims 1, 11-12, 17, 22-23, 26, 30-31, 33, 35-37 and 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,680,426 is obviated by Applicant's cancellation of the claims.
- 9. The rejection of claims 1, 11-12, 17, 22-23, 26, 30-31, 33, 35-37 and 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 7,135,620 is obviated by Applicant's cancellation of the claims.
- 10. The rejection of claims 1, 11-12, 17, 22-23, 26, 30-31, 33, 35-37 and 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 7,294,506 is obviated by Applicant's cancellation of the claims.
- The rejection of claims 1-9, 11-12, 15-23, 25-27, 30-33 and 35-42 on the ground of 11. nonstatutory obviousness-type double patenting as being unpatentable over claims 29-55 of copending Application No. 11/190,122 is obviated by Applicant's cancellation of claims in the instant and copending application.
- The rejection of claims 1, 11-12, 17-26, 30, 33, 35-36-37 and 39 on the ground of 12. nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 28-30 and 32-34 of copending Application No. 10/519,820 is obviated by Applicant's cancellation of the claims.

### Claim Objections

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13. Claim 42 is objected to because of informalities. The objection is repeated for the reasons of record as set forth in the Office action mailed 10 August 2010. Applicant's arguments filed 10 February 2010 have been fully considered but they are not persuasive.

In claim 42 "a" in line 1 should be replaced with --the--.

Applicant urges that the amendments overcome the objection (response pg 4).

This is not found persuasive because while the amendments overcome the objection to claim 32 and obviated the objection to claim 35, the amendments did not overcome the objection to claim 42.

# Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 15. Claims 27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniell (WO 99/10513) taken with the evidence of the instant specification. The rejection is repeated for the reasons of record as set forth in the Office action mailed 10 August 2010, as applied to claims 1-4, 7, 16-17, 20-23, 26-27, 30-33, 35-37 and 39. Applicant's arguments filed 10 February 2010 have been fully considered but they are not persuasive.

Daniell discloses a plastid transformation vector comprising a first flanking sequence (rbcL or 16S/trnI), a promoter (Prrn or PatpB), a selectable marker (aadA, which encodes an aminoglycodase), a heterologous DNA coding for a foreign gene (EPSPS, EG121, mGFP4, hph,

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CryIIA), a 3' UTR (psbA 3'), and a second flanking sequence (ORF512 or trnA) (Fig. 2-3, 5-8). Both sets of flanking sequences are conserved in the plastid genome of higher plant species (pg 20, lines 20-34) and are transcriptionally active spacer regions (pg 9, lines 6-22). The instant specification teaches that the Prn promoter is functional in green and non-green plastids, that is, in light and dark (pg 39, lines 4-7), and that the psbA 3' UTR provides transcript stability to the DNA coding for a foreign gene (pg 44, line 32, to pg 45, line 1).

Daniell also discloses Arabidopsis plants whose plastids are transformed via their roots with the vectors (pg 50, lines 17-21). Daniell also discloses somatic embryos transformed with the vectors (pg 50, line 17, to pg 51, line 4). Further, all the plants whose plastids are transformed with these vectors in Daniell (pg 42-51) would have roots and other non-green plant parts whose plastids comprise the vector; these non-green plant parts would be capable of regenerating through somatic embryogenesis. Green or non-green plant cells transformed with the vector that are regenerated via somatic embryogenesis would be structurally identical to green or non-green plant cells, respectively, transformed with the vector that are not regenerated via somatic embryogenesis. Daniell et al discloses progeny and seeds of plants transformed with one of the vectors (pg 59, line 32, to pg 60, line 9). Growing the plant cells would express the protein of interest.

Applicant urges that the amendments obviate the rejection, and that a Declaration will follow (response pg 4).

This is not found persuasive because the amendments do not obviate the rejection, and no Declaration was sent.

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# Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 17. Claims 27, 32, 40 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) in view of Adams et al (1999, US Patent 5,919,675) and taken with the evidence of Daniell (US Patent 7,129,391). The rejection is repeated for the reasons of record as set forth in the Office action mailed 10 August 200, as applied to claims 1-4, 7, 16-17, 20-23, 26-27, 30-33, 35-37 and 39-42. Applicant's arguments filed 10 February 2010 have been fully considered but they are not persuasive.

The claims are drawn to plastid transformation vectors and a method of plastid transformation comprising transforming the plastids of a plant cell with the vector, and culturing the resulting transplastomic cell in the presence of the selection agent to allow the cell to form a somatic embryo, which is then regenerated into a transplastomic plant.

The teachings of Daniell (WO 99/10513) are discussed above. Daniell ('391, which has the same specification as WO 99/10513) shows that WO 99/10513 teaches the transformation of maize plastids (claims 72-74, 78-80, 91).

Daniell (WO 99/10513) does do not teach culturing the transplastomic cell in the presence of the selection agent to allow the cell to form a somatic embryo, which is then regenerated into a transplastomic plant.

Adams et al teach culturing the maize cells transformed via particle bombardment in the presence of the selection agent to allow the cell to form a somatic embryo, which is then regenerated into a transformed plant (column 30, line 6, to column 34, line 7).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of producing transplastomic maize plants taught by Daniell to use a step in which the transformed maize cell is developed into a somatic embryo before regeneration into a plant as described in Adams et al. One of ordinary skill in the art would have been motivated to do so because Adams et al describe an effective method for producing fertile transformed maize plants.

Applicant urges that the amendments and Daniell Declaration obviate the rejection, and that Adams does not cure the deficiencies of Daniell, as it does not teach plastid transformation (response pg 4).

This is not found persuasive because the amendments do not obviate the rejection, and no Declaration was sent. Adams is cited for teaching selection, not plastid transformation.

### Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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April 5, 2010

/Anne R Kubelik/ Primary Examiner, Art Unit 1638